

**PROPOSED AMENDED PATIENT INFORMATION LEAFLET (CLEAN)**

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**AURO-AMOXICLAV 125-31.25 mg/5 ml** (Powder for oral Suspension)

**AURO-AMOXICLAV 250-62.5 mg/5 ml** (Powder for oral Suspension)

Amoxicillin and clavulanic acid

**Read all of this leaflet carefully before you start taking this medicine.**

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- This medicine has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

**1. WHAT AURO-AMOXICLAV CONTAINS**

The active substances are amoxicillin and clavulanic acid.

**AURO-AMOXICLAV 125-31.25 mg/5 ml:**

Each 5 ml (after reconstitution) contains: Amoxicillin trihydrate, equivalent to amoxicillin 125 mg and potassium clavulanate equivalent to clavulanic acid 31.25 mg

**AURO-AMOXICLAV 250-62.5 mg/5 ml:**

Each 5 ml (after reconstitution) contains: Amoxicillin trihydrate, equivalent to amoxicillin 250 mg and potassium clavulanate equivalent to clavulanic acid 62.5 mg

The other ingredients contained in **AURO-AMOXICLAV** are aspartame, hypromellose, silica colloidal anhydrous, silicon dioxide, strawberry guarana flavour, succinic acid, syloid, and xanthum gum.

**2. WHAT AURO-AMOXICLAV IS USED FOR**

**AURO-AMOXICLAV** is a combination of a penicillin, amoxicillin and a beta-lactamase inhibitor, clavulanic acid. Penicillins and beta-lactamase inhibitors are used to treat many different infections caused by bacteria, such as sinusitis, bronchitis, pneumonia, tonsillitis, ear infections, urinary tract infections and infections of the skin. Amoxicillin works by killing the bacteria. Clavulanic acid is added

to the amoxicillin to protect the amoxicillin from certain substances (enzymes) that will destroy the amoxicillin before it can kill the bacteria.

### 3. BEFORE YOU TAKE AURO-AMOXICLAV

#### Do not take AURO-AMOXICLAV:

- If you have ever had an allergic reaction to amoxicillin, to any other penicillin antibiotic, or to a cephalosporin antibiotic.
- If you have previously had jaundice (yellow pigmentation of skin and eyes) and/or liver disease when using the combination of amoxicillin and clavulanic acid.

#### Take special care with AURO-AMOXICLAV:

- A serious form of diarrhoea (pseudomembranous colitis) may occur. Contact your doctor right away if stomach pain or cramps, severe diarrhoea, or bloody stools occur.
- If you are taking high doses, make sure you drink plenty of fluids.
- Keep all appointments with your doctor and laboratory. If you are taking **AURO-AMOXICLAV** for a long period of time, your doctor may order certain tests to check your kidneys, liver and blood.
- If you are having tests on or checking your urine for sugar, let the doctor know that you are on **AURO-AMOXICLAV**. This is because **AURO-AMOXICLAV** can affect the results of these tests.
- Use of **AURO-AMOXICLAV** may result in an infection that occurs while you are being treated for an infection. If this occurs, **AURO-AMOXICLAV** should be stopped and suitable treatment given.

Before using **AURO-AMOXICLAV**, tell your doctor if you:

- have allergies or a history of allergies – Patients with a history of allergies are more likely to have a allergic reaction to **AURO-AMOXICLAV** which can be serious and possibly fatal. Tell your doctor about any previous allergic reactions to penicillins, cephalosporins, other medicines, food, or other substances.

Stop taking **AURO-AMOXICLAV** and get emergency help if you have any of these signs of an allergic reaction: hives; difficulty breathing; swelling of your face, lips, tongue or throat.

- have infectious mononucleosis (glandular fever) or a sore throat.
- have syphilis
- have lymphatic leukemia (cancer of the blood)
- have liver disease
- have kidney disease
- are breast-feeding
- have a blood clotting disorder

**Taking AURO-AMOXICLAV with food:**

**AURO-AMOXICLAV** should be taken immediately before a meal.

**Pregnancy and Breast-feeding:**

- The safety of this medicine in pregnant women has not been confirmed - Tell your doctor if you are pregnant or plan to become pregnant.
- **AURO-AMOXICLAV** can pass into breast milk and may cause a yeast infection, diarrhoea, or allergic reaction in a nursing baby. Do not use this medication without telling your doctor if you are breast-feeding a baby.

If you are pregnant or breast feeding your baby, please consult your doctor, pharmacist or other health care professional for advice before taking this medicine.

**Taking other medicines with AURO-AMOXICLAV:**

Some medicines may interact with amoxicillin and clavulanic acid. Before taking **AURO-AMOXICLAV**, tell your doctor if you are using any of the following medicines:

- oral contraceptives – Your oral contraceptive may not work properly. You will need to use extra contraceptive precautions, such as using a condom. If you need any advice, talk to your doctor or pharmacist.
- allopurinol, a medicine used for gout.
- any medicine to stop blood clots, such as warfarin.

- tetracycline antibiotics.
- another antibiotic.

If you are using any of these medicines, you may not be able to take **AURO-AMOXICLAV**, or you may need dosage adjustments or your doctor may need to monitor you carefully for side-effects.

If you are taking other medicines on a regular basis, including complementary or traditional medicines, the use of **AURO-AMOXICLAV** with these medicines may cause undesirable interactions. Please consult your doctor, pharmacist or other healthcare professional, for advice.

#### 4. HOW TO TAKE AURO-AMOXICLAV

Always take **AURO-AMOXICLAV** exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure. If you have the impression that the effect of **AURO-AMOXICLAV** is too strong or too weak, talk to your doctor or pharmacist.

- **AURO-AMOXICLAV** should be taken at the start of a meal, to help prevent stomach upset.
- Shake the liquid well before each use to mix the medication evenly.
- To be sure you get the correct dose, measure the liquid with a marked measuring spoon.
- Take this medication for the entire length of time, prescribed by your doctor.
- The usual dose of **AURO-AMOXICLAV** in children is 25 - 50 mg/kg/day, taken in divided doses every 8 hours (three times a day).
- The dose for children is based on body weight and must be determined by your doctor.
- Tell your doctor if you suffer from kidney disease – your dosage may need to be adjusted.

#### **If you take more AURO-AMOXICLAV than you should:**

Overdose symptoms may include queasiness or feeling that one is about to vomit, vomiting, diarrhoea, or crystals in the urine, which may be seen as cloudy urine, or problems passing urine.

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

**If you forget to take AURO-AMOXICLAV:**

Take the missed dose as soon as you remember it. However, if it is almost time for the next dose, skip the missed dose and continue your regular dosing schedule. Do not take a double dose to make up for a missed one.

**5. POSSIBLE SIDE-EFFECTS**

**AURO-AMOXICLAV** can have side-effects.

Get emergency medical help at once if you have any of these signs of an allergic reaction:

- hives
- difficulty breathing
- swelling of your face, lips, tongue, or throat.

Call your doctor at once if you have any of these serious side-effects:

- high temperature (fever), chills, a sore throat or other signs of an infection, or if you bruise easily.  
These may be signs of a problem with your blood cells.
- Unusual bleeding - your blood may take longer to clot than it normally would. You may notice this if you cut yourself or have a nosebleed.
- pale skin, excessive tiredness.
- a delayed allergic reaction, some signs include: rashes, fever, joint pains and enlargement of the lymph nodes.
- a skin reaction known as "erythema multiforme", where you may develop: itchy reddish purple patches on the skin. You may have a fever and be very tired.
- other severe skin reactions can include: changes in skin colour, bumps under the skin, blistering, pustules, peeling, redness, pain, itching, scaling. These may be associated with fever, headaches, and body aches.

- rash or pinpoint flat red round spots under the skin surface or bruising of the skin. This is due to inflammation of blood vessel walls due to an allergic reaction. It can be associated with joint pain and kidney problems.
- convulsions (seizures), seen in patients on high doses or with kidney problems.
- nausea, stomach pain, low fever, loss of appetite, yellowing of the skin or eyes, dark urine, or clay-coloured stools.
- inflammation of the large bowel (colon) with severe diarrhoea that is watery or bloody, pain and fever.
- urinating less than usual or not at all.

Other possible side-effects are:

- mild skin rash
- hyperactivity
- dizziness
- headache
- feeling sick (nausea)
- being sick (vomiting)
- diarrhoea
- stomach/abdominal pain
- indigestion
- taste disturbances
- teeth may appear stained, usually returning to normal with brushing
- sore mouth or tongue
- black, or "hairy" tongue
- thrush (white patches inside your mouth)
- vaginal itching or discharge
- hot flushes
- crystals in the urine, which may be seen as a cloudy urine, or difficulty or discomfort in passing urine. Make sure you drink plenty of fluids to reduce the chance of these symptoms.

Tell your doctor if any of the above side-effects are severe, bothersome, do not go away or about any concerns you have while taking **AURO-AMOXICLAV**.

Not all side effects reported for this medicine are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking this medicine, please consult your doctor, pharmacist or other health care professional for advice.

## 6. STORING AND DISPOSING OF AURO-AMOXICLAV

**Store all medicines out of the reach of children.**

For dry powder:

Store below 30 °C (room temperature) and away from moisture (not in the bathroom).

For reconstituted suspension:

Once reconstituted, the suspension (liquid medication) should be kept in a refrigerator. Throw away any unused medication after 7 days. Do not freeze. Shake the bottle well before use.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

## 7. PRESENTATION OF AURO-AMOXICLAV

### **AURO-AMOXICLAV 125-31.25 mg/5 ml:**

One 150 ml heavy weight HDPE translucent, round bottle closed with a screw cap packed in a printed carton with a package insert.

(100 ml of suspension after reconstitution)

One 200 ml Amber coloured, round glass bottle closed with a screw cap packed in a printed carton with a package insert.

(100 ml of solution after reconstitution).

### **AURO-AMOXICLAV 250-62.5 mg/5 ml:**

One 150 ml heavy weight HDPE translucent, white opaque round bottle closed with a screw cap packed in a printed carton with a package insert.

(100 ml of suspension after reconstitution).

**Applicant/PHC: AUROGEN SOUTH AFRICA (PTY) LTD**

**Product proprietary name: AURO -AMOXICLAV 125-31.25 mg /5 ml / 250 mg 62.5 mg /5 ml**

**Dosage form and strength: POWDER FOR SUSPENSION 125-31.25 mg /5 ml / 250 mg 62.5 mg /5 ml**

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One 200 ml Amber coloured, round glass bottle closed with a screw cap packed in a printed carton with a package insert.

(100 ml of solution after reconstitution)

## **8. IDENTIFICATION OF AURO-AMOXICLAV**

### **AURO-AMOXICLAV 125-31.25 mg/5 ml:**

White to off white granular powder forming a white to off white suspension with a strawberry flavour on constitution with water.

### **AURO-AMOXICLAV 250-62.5 mg/5 ml:**

White to off white granular powder forming a white to off white suspension with a strawberry flavour on constitution with water.

## **9. REGISTRATION NUMBERS/REFERENCE NUMBERS**

**AURO-AMOXICLAV 125-31.25 mg/5 ml: 41/20.1.2/0963**

**AURO-AMOXICLAV 250-62.5 mg/5 ml: 41/20.1.2/0964**

## **10. NAME AND ADDRESS OF REGISTRATION HOLDER**

Aurogen South Africa (Pty) Ltd  
Woodhill Office Park, Building 1,  
53 Phillip Engelbrecht Avenue,  
Meyersdal, Ext. 12,  
1448,  
Johannesburg,  
South Africa

## **11. DATE OF PUBLICATION**

17 April 2009

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